

NOV 17 1997



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT
APPLICATIONIn re Patent Application
of Inventor(s) LEE
Appln. No.08 | 607,485
Series Code ↑ | Serial No. ↑Group Art Unit: 1818
Examiner: M.P. Allen
Atty. Dkt. 220253

Old M#

Filed: February 27, 1996

(Our Deposit Account No. 03-3975)
(Our Order No. 20263)

Title: GDF-1

C#

Client S#
220253SPTO
11/17/97

Date: November 17, 1997

PETITION FOR EXTENSION OF TIME FOR COPENDENCY

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

Sir:

Applicant hereby petitions to extend the life of this application to and through at least the above dates so as to copend with a continuing application. The requisite extension fee is enclosed.

1. The original due date in the subject application was September 17, 1997.

2. Extension fee required

Large/Small Entity	Fee Code
(1 mo) \$110/\$55	115/215
(2 mos) \$400/\$200	116/216
(3 mos) \$950/\$475	117/217
(4 mos) \$1510/\$755	118/218
+ 200	
-	

3. Enter any previous extension fee paid since last Action..... subtract

CHECK ATTACHED FOR FEE OF

\$200

4. "Small entity" verified statement filed: herewith. previously.

Please charge any missing or inadequate fee re this petition to our Deposit Account/Order Nos. shown in the heading hereof for which purpose a duplicate copy of this sheet is attached:

Cushman Darby & Cushman
Intellectual Property Group of
Pillsbury Madison & Sutro LLP

1100 New York Avenue, N.W.
Ninth Floor, East Tower
Washington, D.C. 20005-3918
Tel: (202) 861-3000
PNK/ms

By: Atty: Paul N. Kokulis Reg No. 16,773Sig: Paul N. Kokulis Fax: (202) 822-0944
Tel: (202) 861-3503

12/10/1997 DBUTLER 00000000000000000000000000000000
01 FC4216 NOTE: This paper must be headed in the parent application of, and filed in duplicate and separately
from, Rule 60(b) continuation, division or CIP papers, with separate PTO receipt (CDC-103A).



**IN THE UNITED STATES PATENT AND TRADEMARK
OFFICE**
**REQUEST FOR FILE WRAPPER CONTINUING APPLICATION UNDER 37 CFR 1.62
(RULE 62)**

For Design or Utility Applications

BOX FWC

The Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

Prior Application: 08/607,485

Group Art Unit: 1818

Examiner: M.P. Allen

Atty Dkt: 241801/

new M#/Client Ref.

(Our Deposit Account No. 03-3975

(Our Order No. 20263/241801

C# / new M#

series code ↑ ↑ serial no. Date: November 17, 1997

Sir:

This is a **RULE 62 REQUEST** for filing from

prior copending parent Application No. 08/607,485

, a

□ divisional

continuation (Exr. NOTE: any election in parent as to species/restriction requirement:

is carried over with traverse is not carried over)

continuation-in-part without new Declaration (Rule 62(d)) without fee

continuation-in-part (with new Declaration attached hereto)

The parent was filed on February 27, 1996, entitled GDF-1,

by the following named inventor(s) who is/are the same as, less than all of (see Item 17),

more than (for CIP only), those named in that parent application:

(1) Inventor	Se-Jin	LEE
First	Middle Initial	Family Name
Residence	Baltimore, Maryland	Maryland, USA
City	State/Foreign Country	Country of Citizenship

Post Office Address	2509A Steele Road, Baltimore, Maryland
(include Zip Code)	21209

(2) Inventor			
First	Middle Initial	Family Name	
Residence			
City	State/Foreign Country	Country of Citizenship	

Post Office Address	
(include Zip Code)	

(3) Inventor			
First	Middle Initial	Family Name	
Residence			
City	State/Foreign Country	Country of Citizenship	

Post Office Address	
(include Zip Code)	

(4) Inventor			
First	Middle Initial	Family Name	
Residence			
City	State/Foreign Country	Country of Citizenship	

Post Office Address	
(include Zip Code)	

(5) Inventor			
First	Middle Initial	Family Name	
Residence			
City	State/Foreign Country	Country of Citizenship	

Post Office Address	
(include Zip Code)	

NOTE: FOR ADDITIONAL INVENTORS, check box and attach sheet (CDC-110A) with same information with
same information for each inventor starting with inventor No. 6 and number new page 1A.

1. **Requirement of Rule 62:** Rule 62 filings are to be used only when the issue fee has not been paid (except as noted below) in the above-identified prior application nor that application abandoned or its proceedings terminated. This Rule 62 filing will be considered by the PTO as an express abandonment of that prior application except when this Rule 62 filing is pursuant to Rule 313(b)(5), i.e., when the issue has been paid in the prior application and a petition filed to abandon that application to permit an IDS to be considered in this Rule 62 application. (Note: 37 CFR 1.53 (Rule 53) may be used for continuations and divisions where the prior application is not to be abandoned.)

2. The issue fee has been paid in the parent, but this Rule 62 Request follows a Rule 313(b)(5) petition, and per 1138 OG 40 waiver is respectively requested of that part of Rule 62 which prohibits use of the rules to file an FWC after payment of the issue fee.

3. Priority is claimed under 35 U.S.C. 119/365 based on filing in _____ of _____ (country)

Application No.	Filing Date	Application No.	Filing Date
-----------------	-------------	-----------------	-------------

(1) _____	_____	(4) _____	_____
(2) _____	_____	(5) _____	_____
(3) _____	_____	(6) _____	_____

a. (No.) Certified copy/copies attached.

b. Certified copy/copies previously filed on _____ in prior U.S. Application No. _____ / _____, filed on _____

series code \uparrow \downarrow serial no.

c. Certified copy/copies filed during International stage of PCT/ _____ / _____

d. Priority is also claimed from PCT/ _____ / _____ filed _____

4. The prior application is assigned of record to Carnegie Institute of Washington by Assignment recorded January 16, 1991 Reel 5582 Frame 797.

5. Attached is an assignment Cover Sheet.

Please return the recorded Assignment to the undersigned.

6. The power of attorney in the prior application is to Paul N. Kokulis, Reg. No. 16,773
CUSHMAN DARBY & CUSHMAN IP GROUP OF PILLSBURY MADISON & SUTRO LLP
(Name, Reg. No.) \uparrow

7. Recognize as associate attorney _____

(Name and Reg. No.; Address as in item 8 unless otherwise indicated) \uparrow

8. **Address all future communications to Cushman Darby & Cushman, Intellectual Property Group of Pillsbury Madison & Sutro LLP, Ninth Floor, East Tower
1100 New York Avenue, N.W., Washington, D.C. 20005-3918**

9. Amend the specification by inserting before the first line (in place of any comparable insert previously requested in any prior application) the sentence: --This is a

continuation-in-part (CIP) continuation division

of application No. 08/607,485, filed on February 27, 1996, which was
series code \uparrow \downarrow serial no.

abandoned upon the filing hereof, which is a division of Serial No. 08/583,491, filed January 5, 1996, now abandoned, which is a continuation of Serial No. 08/316,456, filed October 3, 1994, now abandoned, which is a continuation of Serial No. 08/900,002, filed July 12, 1993, now abandoned, which is a continuation of Serial No. 07/614,452, filed November 16, 1990, now abandoned, which is a continuation-in-part of Serial No. 07/538,372, filed June 15, 1990, now abandoned,

10. 1 (No.) Verified Statement(s) establishing "small entity" status under Rules 9 and 27
a. filed in above prior application (and hence applicable hereto)
b. attached.

11. **Requirement of Rule 62:** It is understood that secrecy under 35 U.S.C. 122 is hereby waived to the extent that if information or access is available to any one of the applications in the file wrapper of a 37 CFR 1.62 application, be it either this application or a prior application in the same file wrapper, the Patent and Trademark Office may provide similar information or access to all the other applications in the same file wrapper.

12. Petition to extend the life of the above prior application to at least the date hereof

NOTE: is being concurrently filed in that prior application (Use Form CDC-111).
 (must be) was previously filed in that prior application (Check length of prior extension).
 (X'd) is not necessary for copendency (Double check before X'ing this box).

13. Please enter the amendment previously filed on _____ but unentered in the above prior application.

14. Attached: _____ sheet(s) per set of drawing of Fig(s) :
 1 set informal; formal of size: A4 11"

15. **PRELIMINARY AMENDMENT to be entered before fee calculation** (Do not make amendments here except cancellation of whole claims or multiple dependencies for purpose of reducing the filing fee per MPEP §§ 506 and 607; do not cancel all claims.):

16.* Attached is a Rule 103(a) Petition to suspend action

17. Petition is hereby made requesting deletion as inventor(s) of the following who is/are not inventor(s) of the invention being claimed in this Rule 62 application:

1. _____ 2. _____
 3. _____ 4. _____

18. This Rule 62 application is a continuation-in-part which discloses and claims additional matter and the amendments in attached Amendment are to be considered an integral part of the CIP ab initio.
 a. New Declaration is attached.
 b. This application is also filed under Rule 62(d) (without a Declaration) and hence filing fee is not enclosed.

FILING FEE

THE FOLLOWING FILING FEE IS BASED ON THE CLAIMS
 EXISTING IN THE PRIOR APPLICATION AS AMENDED AT 13 AND 15 ABOVE

			Large/Small Entity	Fee Code
19. Basic Filing Fee		Design Application	\$330/\$165	106/26
20.		Not Design Application	\$790/\$395	101/201
21. Total Effective Claims	7	minus 20 = 0	x \$22/\$11	+0
(Base this on claims as amended to effect CIP if this is a Rule 62(d) completion)				
22. Independent Claims	2	minus 3 = 0	x \$82/\$41	+0
23. If any proper multiple dependent claim (ignore improper) is present, (Leave this line blank if this is a reissue application)			\$270/\$135	+0
24.	TOTAL FILING FEE = \$395			
25. If "assignment" box 5 is X'd, add recording fee.			\$40	+ 581
26. If "petition" box 16 above is X'd, add petition fee.			\$130	+130 122
27.	FEES ATTACHED = \$525			
	(carry forward to line 36)			

28. Preliminary Amendment attached (to be entered after assigning Appln. No.).
(Do NOT X box 28 or 29 for CIP Amendment. See box 18)

29. The following PRELIMINARY AMENDMENT is to be entered after assigning Appln. No..

30. ATTACHED:
PRELIMINARY AMENDMENT and REQUEST FOR SUSPENSION OF ACTION

**ADDITIONAL FEE CALCULATION FOR
PRELIMINARY AMENDMENT
PER BOXES 28/29**

Claims remaining after amendment	Highest number previously paid for	Present Extra	Additional Fee
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		<u>Large/Small Entity</u>	File Code
32.	Total Effective Claims <u>9</u>	minus ** <u>20</u> = * <u>0</u> x \$22/\$11 = <u>\$ 0</u>	(103/203)
33.	Independent Claims <u>2</u>	minus *** <u>3</u> = * <u>0</u> x \$82/\$41 = <u>+ 0</u>	(102/202)
34.	If amendment enters proper multiple dependent claim(s) into this application for the <u>first time</u> , add	\$270/\$135(per application)	+ <u>0</u> (104/204)
35.		ADDITIONAL FEE	<u>\$ 0</u>
36.		plus FEE from item 27 on page 3	<u>+ 525</u>
37.		<u>TOTAL FEE ATTACHED</u>	<u>\$ 525</u>

38. *If the entry in the first space is less than an entry in the middle space, the "Present Extra" result is "0"

39. **If the "Highest number previously paid for" (see item 21 above) is less than 20, write "20" in this space

40. If the "Highest number previously paid for" (see item 22 above) is less than 3, write "3" in this space

CHARGE STATEMENT: The Commissioner is hereby authorized to charge any fee specifically authorized hereafter, or any missing or insufficient fee(s) filed, or asserted to be filed, or which should have been filed herewith or concerning any paper filed hereafter, and which may be required under Rules 16-18 (missing or insufficient fee only) now or hereafter relative to this application and the resulting Official document under Rule 20, or credit any overpayment, to our Account/Order Nos. shown in the heading hereof for which purpose a duplicate copy of this sheet is attached. This CHARGE STATEMENT does not authorize charge of the issue fee until/unless an issue fee transmittal form is filed.

Cushman Darby & Cushman

Intellectual Property Group of

Pillsbury Madison & Sutro LLP

By: Atty: Paul N. Kokulis

1100 New York Avenue, N.W.
Ninth Floor East Tower
Washington, D.C. 20005-3918
Tel: (202) 861-3000
PNK/ms

Reg. No. 16,773

Sig: Paul N. Kokulis

Fax: (202) 822-0944

Tel: (202) 861-3503

NOTE: No: 1: File this Request in duplicate with 2 postcard receipts (CDC-103) & attachments

NOTE: No: 2: Is extension in parent necessary for copendency? **DOUBLE CHECK** Item 12 above.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

LEE

FWC of Appln. No. 08/607,485

Group Art Unit: 1818

Filed: November 17, 1997

Examiner: M. Allen

FOR: GDF-1

* * *

November 17, 1997

REQUEST FOR SUSPENSION OF ACTION

Honorable Commissioner of
Patents and Trademarks
Washington, D.C. 20231

Sir:

In accordance with the provisions of 37 C.F.R. 1.103(a), request by way of petition is hereby made to suspend action on the above-referenced application by the U.S. Patent and Trademark Office for a period of six months, up to and including May 17, 1998, based on the following showing of good and sufficient reasons.

A file wrapper continuing (FWC) application under 37 C.F.R. 1.62 is being filed together with this petition. Therefore, no response by applicant to an Office Action is required.

12/10/1997 DEUTLER 00000042 08971338
02 FC:122 In the Office Action of May 17, 1997, the Examiner has maintained her rejection of the claims under 35 U.S.C. 112, first paragraph. The Examiner's position appears to be that the specification's disclosure of how the claimed invention is to be used is not credible in the absence of declaration

ATTORNEY-CLIENT/WORK PRODUCT

evidence supporting those uses. Although this position is disputed, such evidence is currently being obtained in the interest of furthering prosecution in this application.

In view of time required to produce GDF-1, establish an assay which would support use of GDF-1 as disclosed in the specification, collect data from the assay, and prepare a declaration based on the data, applicant requests suspension of action so that the necessary data may be presented to the Examiner prior to a first Office Action on the merits. Like the recombinant production of GDF-1, assays which would establish the biological activity of GDF-1 are known in the art. Applicant submits that such declaration evidence will allow the Examiner to withdraw the enablement rejection and allow the pending claims.

Thus, it is the intent of the undersigned to place the present application in the best posture for further consideration by the Examiner.

The fee as required by 37 C.F.R. 1.17(i) is enclosed herewith. If this fee is missing or insufficient, the Office is hereby authorized to charge our Deposit Account No. 03-3975, Order No. 20263/241801 for the missing or insufficient amount, for which purpose a duplicate copy of this paper is attached.

52747857.359.142

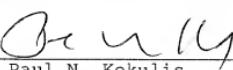
LEE - FWC of Appln. No. 08/607,485

Prompt consideration of this petition and a favorable response are earnestly requested. The Office is invited to contact the undersigned if further information is needed.

Respectfully submitted,

Cushman Darby & Cushman
Intellectual Property Group of
PILLSBURY MADISON & SUTRO, L.L.P.

By



Paul N. Kokulis
Reg. No. 16,773
Telephone: (202) 861-3503
Facsimile: (202) 822-0944

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1100 New York Avenue, N.W.
Ninth Floor, East Tower
Washington, D.C. 20005-3918
Phone: (202) 861-3503

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

LEE

FWC of Appln. No. 08/607,485

Group Art Unit: 1818

Filed: November 17, 1997

Examiner: M. Allen

FOR: GDF-1

★ ★ ★

November 17, 1997

PRELIMINARY AMENDMENT

Honorable Commissioner of
Patents and Trademarks
Washington, D.C. 20231

Sir:

Entry and consideration of the following amendment and
remarks prior to examination are respectfully requested.

IN THE CLAIMS:

Please add the following claims.

--22. The protein according to claim 4 wherein said protein has a molecular weight of 41K or 38K as shown in Figure 4.

23. The protein according to claim 9 wherein said protein has a molecular weight of 41K or 38K as shown in Figure 4 --

REMARKS

The Examiner's attention is directed to the accompanying petition submitted under 37 C.F.R. 1.103(a); the petition requests suspension of action in the present application. A decision on this petition is requested prior to examination and issuance of a first Office Action. Further, if the declaration to be submitted prior to May 17, 1998 has not reached the Examiner when this application is taken up for examination, she is invited to contact the undersigned.

Claims 4-10 and 22-23 are pending. New claims 22-23 are directed to GDF-1 protein lacking a signal peptide as shown by *in vitro* translation of full-length GDF-1 transcript in the presence of dog pancreas microsomes (Example 2).

The amendments to the claims find support throughout the original disclosure and, thus, do not introduce new matter. See, in particular, pages 20-22 of the specification.

Claims 4-10 were rejected under 35 U.S.C. 112, first paragraph, as allegedly "containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention". Applicant traverses.

Contrary to the statement on pages 2-3 of the Office Action (Paper No. 4), applicant does not agree with the Examiner that uses of the claimed invention discussed in the

4527471338119680

previous Office Action are not enabled. Applicant is not arguing that a person skilled in the art would have to "dream up" potential uses of the present invention. Instead, applicant submits that the Examiner has not explained in previous Office Actions why the objective truth contained in the disclosure is doubted by "evidence or reasoning which is inconsistent with the contested statement". M.P.E.P. 2164.01 and *In re Marzocchi*, 169 U.S.P.Q. 367, 370 (C.C.P.A. 1971). No such evidence or reasoning was given in the previous Office Actions, the Examiner merely stated her belief that "it could not be predicted which activity GDF-1 would have, if any" (page 2 of Paper No. 3). Thus, the Examiner's objection appears to be based on the lack of working examples in the specification. However, applicant submits that working examples are not required in order to comply with Section 112, first paragraph, (M.P.E.P. 2164.02) especially in view of the other examples provided in the specification.

Although applicant maintains that this is sufficient to overcome the Examiner's objection to the specification, a declaration is being prepared to further prosecution in the present application. As discussed in the petition, suspension is requested to allow applicant time to prepare a declaration containing evidence responsive to the pending enablement rejection. Such declaration evidence should be further considered as a response to the pending enablement rejection.

Finally, it is noted that the Hoben et al. reference supports the use of GDF-1 as a lineage marker because of its expression "primarily in the nervous system". Further, the cited abstract does not support the Examiner's allegation that "biological activity, and assays therefore, for GDF-1 had not been determined at the time of the invention" (page 5 of the Office Action, Paper No. 4). Instead the abstract describes further characterization of GDF-1 and studies showing that recombinant GDF-1 "stimulates the expression of the immediate early genes in neural cell lines". Thus, one would not conclude from the abstract that GDF-1 does not have a biological activity or that such activities as disclosed in the present application are incredible.

A favorable action on the merits is earnestly requested. If any further information is required, the Examiner is invited to contact the undersigned.

Respectfully submitted,

Cushman Darby & Cushman
Intellectual Property Group of
PILLSBURY MADISON & SUTRO, L.L.P.

By


Paul N. Kokulis
Reg. No. 16,773
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1100 New York Avenue, N.W.
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Phone: (202) 861-3503

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

LEE

FWC of Appln. No. 08/607,485

Group Art Unit: 1818

Filed: November 17, 1997

Examiner: M. Allen

FOR: GDF-1

* * *

November 17, 1997

REQUEST FOR SUSPENSION OF ACTION

Honorable Commissioner of
Patents and Trademarks
Washington, D.C. 20231

Sir:

In accordance with the provisions of 37 C.F.R. 1.103(a),
request by way of petition is hereby made to suspend action on
the above-referenced application by the U.S. Patent and
Trademark Office for a period of six months, up to and
including May 17, 1998, based on the following showing of good
and sufficient reasons.

A file wrapper continuing (FWC) application under 37
C.F.R. 1.62 is being filed together with this petition.
Therefore, no response by applicant to an Office Action is
required.

In the Office Action of May 17, 1997, the Examiner has
maintained her rejection of the claims under 35 U.S.C. 112,
first paragraph. The Examiner's position appears to be that
the specification's disclosure of how the claimed invention is
to be used is not credible in the absence of declaration

AMERICAN INVENTION

evidence supporting those uses. Although this position is disputed, such evidence is currently being obtained in the interest of furthering prosecution in this application.

In view of time required to produce GDF-1, establish an assay which would support use of GDF-1 as disclosed in the specification, collect data from the assay, and prepare a declaration based on the data, applicant requests suspension of action so that the necessary data may be presented to the Examiner prior to a first Office Action on the merits. Like the recombinant production of GDF-1, assays which would establish the biological activity of GDF-1 are known in the art. Applicant submits that such declaration evidence will allow the Examiner to withdraw the enablement rejection and allow the pending claims.

Thus, it is the intent of the undersigned to place the present application in the best posture for further consideration by the Examiner.

The fee as required by 37 C.F.R. 1.17(i) is enclosed herewith. If this fee is missing or insufficient, the Office is hereby authorized to charge our Deposit Account No. 03-3975, Order No. 20263/241801 for the missing or insufficient amount, for which purpose a duplicate copy of this paper is attached.

20263/241801

Prompt consideration of this petition and a favorable response are earnestly requested. The Office is invited to contact the undersigned if further information is needed.

Respectfully submitted,

Cushman Darby & Cushman
Intellectual Property Group of
PILLSBURY MADISON & SUTRO, L.L.P.

By



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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

LEE

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Group Art Unit: 1818

Filed: November 17, 1997

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FOR: GDF-1

* * *

November 17, 1997

PRELIMINARY AMENDMENT

Honorable Commissioner of
Patents and Trademarks
Washington, D.C. 20231

Sir:

Entry and consideration of the following amendment and
remarks prior to examination are respectfully requested.

IN THE CLAIMS:

Please add the following claims.

--22. The protein according to claim 4 wherein said
protein has a molecular weight of 41K or 38K as shown in
Figure 4.

23. The protein according to claim 9 wherein said
protein has a molecular weight of 41K or 38K as shown in
Figure 4.--

08271328.111797

REMARKS

The Examiner's attention is directed to the accompanying petition submitted under 37 C.F.R. 1.103(a); the petition requests suspension of action in the present application. A decision on this petition is requested prior to examination and issuance of a first Office Action. Further, if the declaration to be submitted prior to May 17, 1998 has not reached the Examiner when this application is taken up for examination, she is invited to contact the undersigned.

Claims 4-10 and 22-23 are pending. New claims 22-23 are directed to GDF-1 protein lacking a signal peptide as shown by *in vitro* translation of full-length GDF-1 transcript in the presence of dog pancreas microsomes (Example 2).

The amendments to the claims find support throughout the original disclosure and, thus, do not introduce new matter. See, in particular, pages 20-22 of the specification.

Claims 4-10 were rejected under 35 U.S.C. 112, first paragraph, as allegedly "containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention". Applicant traverses.

Contrary to the statement on pages 2-3 of the Office Action (Paper No. 4), applicant does not agree with the Examiner that uses of the claimed invention discussed in the

65277-00034680

previous Office Action are not enabled. Applicant is not arguing that a person skilled in the art would have to "dream up" potential uses of the present invention. Instead, applicant submits that the Examiner has not explained in previous Office Actions why the objective truth contained in the disclosure is doubted by "evidence or reasoning which is inconsistent with the contested statement". M.P.E.P. 2164.01 and *In re Marzocchi*, 169 U.S.P.Q. 367, 370 (C.C.P.A. 1971).

No such evidence or reasoning was given in the previous Office Actions, the Examiner merely stated her belief that "it could not be predicted which activity GDF-1 would have, if any" (page 2 of Paper No. 3). Thus, the Examiner's objection appears to be based on the lack of working examples in the specification. However, applicant submits that working examples are not required in order to comply with Section 112, first paragraph, (M.P.E.P. 2164.02) especially in view of the other examples provided in the specification.

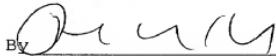
Although applicant maintains that this is sufficient to overcome the Examiner's objection to the specification, a declaration is being prepared to further prosecution in the present application. As discussed in the petition, suspension is requested to allow applicant time to prepare a declaration containing evidence responsive to the pending enablement rejection. Such declaration evidence should be further considered as a response to the pending enablement rejection.

Finally, it is noted that the Hoben et al. reference supports the use of GDF-1 as a lineage marker because of its expression "primarily in the nervous system". Further, the cited abstract does not support the Examiner's allegation that "biological activity, and assays therefore, for GDF-1 had not been determined at the time of the invention" (page 5 of the Office Action, Paper No. 4). Instead the abstract describes further characterization of GDF-1 and studies showing that recombinant GDF-1 "stimulates the expression of the immediate early genes in neural cell lines". Thus, one would not conclude from the abstract that GDF-1 does not have a biological activity or that such activities as disclosed in the present application are incredible.

A favorable action on the merits is earnestly requested. If any further information is required, the Examiner is invited to contact the undersigned.

Respectfully submitted,

Cushman Darby & Cushman
Intellectual Property Group of
PILLSBURY MADISON & SUTRO, L.L.P.


By _____

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